

Notice of Allowability

Application No.

09/662,462

Examiner

Jeanine A Goldberg

Applicant(s)

SMITH ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/8/03; 7/7/03; 10/16/03.
2. ☒ The allowed claim(s) is/are 41 and 43-64.
3. ☒ The drawings filed on 15 September 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |


JEFFREY FREDMAN
PRIMARY EXAMINER

DETAILED ACTION

1. This action is in response to the papers filed July 7, 2003; October 16, 2003.
Currently, claims 41, 43-64 are pending.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance.

The claims are narrowly drawn to oligonucleotides consisting of SEQ ID NO: 2-13 or 33-38 which are species specific probes. The prior art fails to provide an alignment for *Candida albicans*, *Candida parapsilosis*, *Candida tropicalis*, *Candida kefyr*, *Candida krusei*, *Candida glabrata* and *Candida dubliniensis*. While the prior art teaches an alignment of *Candida albicans*, *Candida tropicalis*, and *Candida krusei*, there is no evidence of record that probes to each of the conserved regions would in fact be species specific for each of the species since there is no alignment for all of the *Candida* species which would illustrate which probes would differentiate between the species. Moreover, the art fails to provide any alignment between the other species, thus, there is no suggestion to pick specific probes to these particular sequences of SEQ ID NO: 4-5, 7-8, 10, 11-13, 38

The instant specification provides an assay using LiPA strips containing the species-specific probes of SEQ ID NO: 1-3, 5-6, 9-12. Figure 1 and 2 illustrate the species specific nature of each of these probes, as they only detect the *Candida* species of interest.

Moreover, The Declaration filed by Geert Jannes illustrates that using the probes of Bothelo and Lott in a LiPA hybridization test, does not yield species specific results, as required by the claims.


With respect to the language "the complementary nucleic acid of said SEQ IDS" the specification teaches that the nucleic acid sequences can form perfect base-paired double helix with each other. Thus, "the complementary nucleic" acid has been interpreted to mean the full complement.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
October 21, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER